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Dockets Management Branch
(HFA-305), Food and Drug Administration
5630 Fishers Lane, room 1061,
Rockville, MD 20852.

To Whom It May Concern:

The following letter is written to provide the Agency with comments in reference to the recent Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records docket 00D-1539. The enclosed table contains Barr Laboratories' comments for this guidance. The enclosed table includes the actual text along with the page and section and Barr's comments.

Sincerely,

Ralph Goldstein
Barr Laboratories
Associate Director Applications

00D-1539 C19

Page	Section	Document Text	Comment
7	5.2.1	Factors That Might Affect The Reliability Of Electronic Records During the Required Retention Period Should Be Identified And Controlled. You should identify and control factors that could potentially affect the reliability of electronic records during their records retention periods. These factors include, but are not limited to: •Data encoded within an electronic record (e.g., computer readable representations of information); •Metadata for an electronic record (e.g., information that gives the data meaning and context, such as data dictionaries for databases); •Media (e.g., disk, tape, or flash memory devices) that record data and metadata; •Hardware used to retrieve and display the electronic record; Software (both application programs and operating systems) used to read, process, and display electronic records; and, •The processes of extracting and presenting information in human readable form. If these factors are not controlled properly the information that the electronic records should convey might not be complete, accurate, or usable.	The guidance discusses controls of the identified factors. It should be sufficient to provide the Agency with validation documentation as evidence that the proper controls are in place.
9 /10	5.5	The Ability To Process An Electronic Record's Information Throughout Its Records Retention Period Should Be Preserved. The ability to process information in an electronic record is a key aspect of whether certain electronic records are suitable for FDA inspection and review. Accordingly, where you could use computer technologies to search, sort, or manipulate information in an original electronic record, you should be able to use computer technologies to perform the same kinds of processing on information in the maintained electronic record. For example, if you could automatically search for words in the text of an electronic record, sort or find values in a table, or perform calculations in a spreadsheet, you should be able to process information in a like manner for the electronic record over the entire records retention period.	The objective of this section is to outline the importance of not only maintaining the data but also the ability to read and process the data in the maintained form as in the original. When upgrading an application the vendor may not provide the same exact capability to retrieve and process data in exactly the same way. The guidance should provide leeway to process data in an equivalent manner but not necessarily exactly as in the original application.

Page	Section	Document Text	Comment
11	6	Approaches To Maintenance Of Electronic Records	This section deals with two approaches to maintaining electronic records the first of which is the time capsule approach in which you maintain the existing system without any changes whatsoever during the life of the record. This approach is impractical as Industry would need to keep a "preserved" copy of every version of the software used over the time period covered by the predicate rule. The second method is an electronic records migration approach that is more practical. However the Agency has asked for specific requirements that the Industry may not be able to achieve over the life of an electronic record. Some examples of which would include:
18	6.2.13	"Where a migration, in effect, creates a new electronic record (by transforming the old electronic record) then, per section 11.10(e), the audit trail for the migrated electronic record would have to cover this creation. By adding this new creation step to the migrated audit trail carried over from the old electronic record you will help ensure a continuity of electronic record integrity."	The Agency should consider it sufficient for the upgraded application to retain the pointer or link between the upgraded electronic record and original audit trail record, in cases where an audit trail record existed in the original application. If there was no audit trail required for the original electronic record, no audit trail record should be required as a result of the upgrade.
	6.2.14	In the migration approach, the new computer system should enable you to search, sort and process information in the migrated electronic record at least at the same level as what you could attain in the old system (even though the new system may employ different hardware and software). For example, if you could sort a table of values using the old system, you should be able to sort those values in the migrated electronic record using the new system, and achieve the same results. Some new systems can, by emulating older systems, process information in a very similar way.	The Agency should allow for an equivalent record set without the loss of data as opposed to "same". Industry may not be able to ensure that a new version of an application from a software developer will enable records to be sorted or presented in the exact same way.